PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 5/04 | A1

(11) International Publication Number: WO 00/27279

(43) International Publication Date: 18 May 2000 (18.05.00)

(21) International Application Number: PCT/US99/26459

(22) International Filing Date: 10 November 1999 (10.11.99)

(30) Priority Data:
60/107,918 10 November 1998 (10.11.98) US

(71)(72) Applicant and Inventor: DuROUSSEAU, Donald, R. [US/US]; Suite 1, 37795 Albert's Farm Drive, Purcellville, VA 20132 (US).

(74) Agents: STEWART, David, L. et al.; McDermott, Will & Emery, 600 13th Street, N.W., Washington, DC 20005-3096 (US).

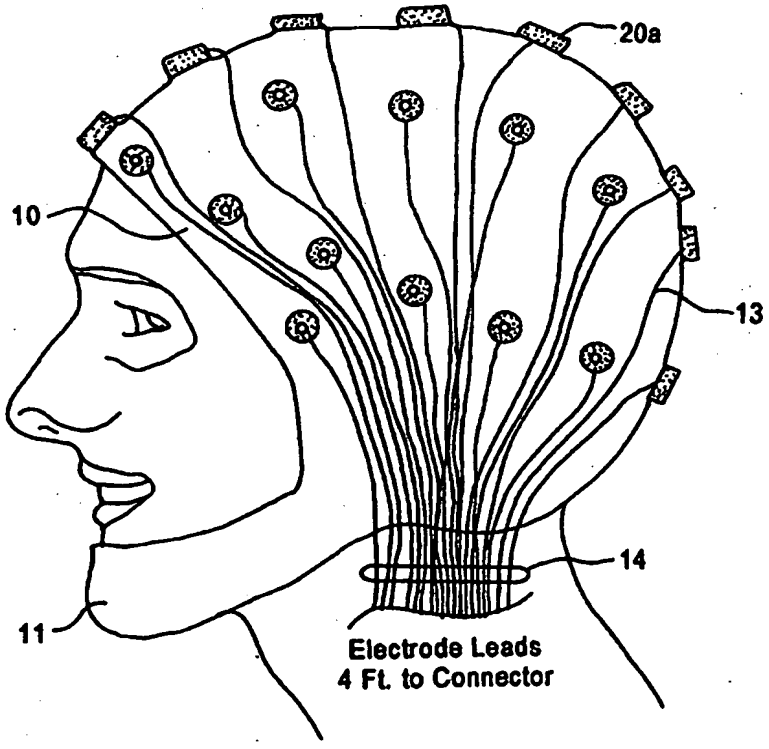
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: fMRI COMPATIBLE ELECTRODE AND ELECTRODE PLACEMENT TECHNIQUES

(57) Abstract

In a brainwave acquisition system, an electrode positioning system includes a stretchable elastic cap (10), soft rubber electrode holders (20a), conductive recording electrodes (not numbered), where the electrodes are composed of materials such as metal, plastic or carbon, and conductive lead wires (13) are composed of materials such as metal or carbon conductive materials. No ferromagnetic materials of any kind are used in the construction of the system, and therefore, the system will not introduce unwanted contamination of functional Magnetic Resonance Imaging (MRI) data.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania
AM	Armenia
AT	Austria
AU	Australia
AZ	Azerbaijan
BA	Bosnia and Herzegovina
BB	Barbados
BE	Belgium
BF	Burkina Paso
BG	Bulgaria
BJ	Benin
BR	Brazil
BY	Belarus
CA	Canada
CF	Central African Republic
CG	Congo
CH	Switzerland
CI	Côte d'Ivoire
CM	Cameroon
CN	China
CU	Cuba
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
GE	Georgia
GH	Ghana
GN	Guinea
GR	Greece
HU	Hungary
IE	Ireland
IL	Israel
IS	Iceland
IT	Italy
JP	Japan
KE	Kenya
KG	Kyrgyzstan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
KZ	Kazakstan
LC	Saint Lucia
LI	Liechtenstein
LK	Sri Lanka
LR	Liberia
LS	Lesotho
LT	Lithuania
LU	Luxembourg
LV	Latvia
MC	Monaco
MD	Republic of Moldova
MG	Madagascar
MK	The former Yugoslav Republic of Macedonia
ML	Mali
MN	Mongolia
MR	Mauritania
MW	Malawi
MX	Mexico
NE	Niger
NL	Netherlands
NO	Norway
NZ	New Zealand
PL	Poland
PT	Portugal
RO	Romania
RU	Russian Federation
SD	Sudan
SE	Sweden
SG	Singapore
SI	Slovenia
SK	Slovakia
SN	Senegal
SZ	Swaziland
TD	Chad
TG	Togo
TJ	Tajikistan
TM	Turkmenistan
TR	Turkey
TT	Trinidad and Tobago
UA	Ukraine
UG	Uganda
US	United States of America
UZ	Uzbekistan
VN	Viet Nam
YU	Yugoslavia
ZW	Zimbabwe

fMRI COMPATIBLE ELECTRODE AND ELECTRODE PLACEMENT TECHNIQUES

Cross Reference to Related Applications

This application claims priority to provisional U.S. patent application Serial Number 60/107,918, filed November 10, 1998 by Don DuRousseau, the contents of which are incorporated herein by reference in their entirety.

Field of the Invention

The present invention relates to medical devices and more specifically to techniques for acquiring uncontaminated electrical signals from the brain and body, without the use of pre-amplification electronics, especially while located within the harsh operating environment produced by a functional magnetic resonance imaging (fMRI) system.

Background of the Related Art

Conventional EEG, EOG, ECG, EMG, and other physiological signals are typically recorded using individually placed electrodes that are fixed on the scalp and body with adhesives or by the use of a cap type system. Examples of these techniques are those developed by Sams et al (U.S. Pat. No. 4,085,739) or Gevins et al (U.S. Pat. No's 4,967,038 and 5,038,782). In these placement methods, the electrodes are attached to amplifiers used to acquire and record the related electrical and physiological activity. These amplifier systems require a very low impedance contact with the skin and are very susceptible to emissions from other electrical equipment, such as an MRI device. In such an environment, the input stage of a conventional EEG, ECG or EMG amplifier is susceptible to the very large induced electrical and magnetic fields generated by a magnetic resonance imager to the point where the amplifier cannot function properly. In addition, these amplifier systems are almost always powered from an AC Voltage source and, therefore, radiate electro-magnetic interference (EMI), which causes contamination of the

anatomical and functional data acquired by the fMRI system and compromises the integrity of these data.

A prior attempt to collect EEG signals within the fMRI environment, by Ives et al (U.S. Pat. No. 5,445,162) is based on a battery powered analog pre-amplifier system in which individual electrodes are glued to the scalp and the electrical activity is amplified within the bore of the imaging device. The signals are then converted to light energy by additional analog circuits placed nearby the patient. While still within the harsh fMRI environment, these signals are communicated along fiber-optic cables outside the shielded room, which protects the imaging equipment from unwanted interference, to a secondary amplifier system that is located outside the shielded room and attached to a PC for collecting and processing the data. However, this optically coupled pre-amplification system is expensive, bulky, and cumbersome to operate. In addition, due to size restrictions within the head coil (located inside the imager) and the inability to use digital circuits in the design, due to broadcast interference from internal clock circuits, the AC-coupled nature of this devices makes it susceptible to large artifacts caused by transient signals produced during normal operation of the imaging system.

Summary of the Invention

The problems of the prior art, described above, are solved, in accordance with the present invention, by providing an EEG Electrode Positioning System using an elastic head cap (hereinafter Quik-Cap), to position electrodes on the head and face to acquire electrical signals and communicate them to external amplifier equipment. The Quik-Cap provides a stretchable elastic cap and chinstrap portion capable of comfortably fitting a wide range of head size and shape variability. The Quik-Cap provides a plurality of electrode holders designed to be filled with a conductive electrolyte. In addition, the Quik-Cap provides a wire harness assembly that can be configured with either carbon or metal lead wires and is capable of interfacing with any type of commercially available amplifier system.

Some specific features and objectives of the invention include the following.

The present invention provides a low cost system for rapidly applying large numbers of electrodes on the head and body that is capable of acquiring signals inside an fMRI system and communicating them outside the shielded environment without the use of any electronic amplification.

It is another objective of the present invention to use carbon lead wires attached to the electrodes positioned on the head and body to limit the susceptibility of the system to contamination from an MRI system and to communicate signals outside a shielded fMRI environment to amplifiers attached to a PC for collecting and processing electrophysiological and other physiologically correlated data.

Another object of the present invention to use metal electrodes composed of Tin, Gold, Silver-Chlorided Silver, or a combination or amalgam of Silver-Chloride powders, each carried in soft rubber electrode mounts and connected to carbon lead wires to limit the susceptibility of the system to physiological and electronically induced contamination.

It is a still further object of the present invention to use carbon, carbonized plastic, or conductive plastic electrodes in connection with carbon lead wires to further limit the susceptibility of the system to physiological and electronically induced contamination.

It is a still further object of the present invention to use needle electrodes, implantible depth electrodes, or cortical surface electrodes in connection with carbon lead wires to further limit the susceptibility of the system to physiological and electronically induced contamination while recording signals directly from the brain or spinal chord.

It is a still further object of the present invention that a single electrode, or group of electrodes, may also be used to acquire signals from the eyes, heart or muscles, by providing a mechanism to position electrodes in the appropriate regions of the scalp, face, chest or body.

Still another object of the present invention is to permit a single lead wire, or group of lead wires, to be used to connect to and communicate signals

from external transducer devices used to measure signals related to oxygen uptake, respiration, heart rate, impedance, motion, acceleration, force or other such signals.

Yet another feature of the present invention is to provide separable elastic cap, chinstrap, and wire harness portions to position electrode holders and electrodes on the head, face and body to acquire EEG, EOG, EMG, ECG and other physiologically correlated signals from humans while inside a magnetic resonance imaging system.

The foregoing and other features, aspects and advantages of the present invention will become more apparent from the following detailed description of the present invention when taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

The objects, features and advantages of the system of the present invention will be apparent from the following description in which:

FIG. 1 is a side view of the elastic cap and chinstrap portion of an exemplary embodiment of the present invention showing electrode holders and lead wire harness assembly in which individual lead wires are attached to electrodes (not shown) carried within the electrode holders.

FIG. 2A is a cross-sectional side view of the electrode holder of FIG. 1.

FIG. 2B is a top plan view of the embodiment of FIG. 2A.

FIG. 2C is a side plan view of the embodiment of FIG. 2A.

FIG. 2D is a top-down view of a rubber O-ring used to attach the electrode holder to the elastic cap portion of FIG. 1.

FIG. 3A is a cross-sectional side view along line A – A of FIG. 3B of an exemplary electrode carried within the electrode holder of FIG. 2A.

FIG. 3B is a top plan view of the embodiment of FIG. 3A.

FIG. 3C is a side plan view of the embodiment of FIG. 3A.

FIG. 4A is a perspective top view of an alternative embodiment of a cup shaped electrode carried in an exemplary electrode holder of FIG 2A.

FIG. 4B is a perspective bottom view of an alternative embodiment using a cup shaped electrode carried in the electrode holder of FIG 2A.

FIG. 4C is a top-down view of the embodiment of the electrode of FIG. 4A.

FIG. 4D is a side view of the embodiment of the electrode of FIG. 4A.

FIG. 4E is a cross-sectional view of an alternative embodiment of a conductive plastic electrode embodiment carried in the electrode holder of FIG. 2A.

FIG. 4F is a top plan view of the embodiment of the electrode in FIG. 4E.

FIG.5A is a top plan view of an alternative embodiment of a conductive plastic electrode embodiment carried in the electrode holder of FIG. 2A.

FIG. 5B is a cross-sectional side view along line B – B of the embodiment of the conductive plastic electrode of FIG. 5A.

FIG.5C is a top plan view of an alternative embodiment of a carbon electrode embodiment carried in the electrode holder of FIG. 2A.

FIG. 5D is a cross-sectional side view along line C – C of the embodiment of the carbon electrode of FIG. 5C.

FIG. 6 is a top plan view of an alternative embodiment of a cortical depth electrode embodiment used with the carbon lead wire harness of the present invention.

FIG. 7 is a top plan view of an alternative embodiment of a cortical surface grid electrode embodiment used with the carbon lead wire harness of the present invention.

FIG. 8 is a top plan view of an alternative embodiment of a cortical surface strip electrode embodiment used with the carbon lead wire harness of the present invention.

Detailed Description of the Preferred Embodiments

As shown in FIG. 1, the fMRI-compatible electrode placement system of the present invention includes an elastic fabric cap portion 10 and chinstrap portion 11, both composed preferably of a combined Lycra-Spandex™ material such as Style #: 96175 Black-09000, manufactured by Liberty Fabrics, 13441 Liberty Lane, Gordonsville, VA). Attached to the elastic cap portion 10, is a plurality of electrode holders 20a-n. The designation "n" means that the number depends on the number of electrodes desired. In typical usage, for example, n may be in the range from 1 to 1024. Also in FIG. 1, a plurality of lead wires 13 of the present invention form a harness assembly 14. The lead wires may be constructed of any non-ferromagnetic conductive material, but are preferably made of carbon. The lead wires may be wrapped in groups with flexible wrapping material (not shown), and extend from the electrodes (not shown) carried within the electrode holders 20a-n away from the head, terminating in a connector, such as a CHG-Series 40 pin connector (not shown) manufactured by 3M, Inc. The flexible wrapping (not shown) is used to ensure the wires will not be allowed to coil while inside the MRI environment in order to prevent induced heating of the lead wire material.

As shown in FIGS. 2A – 2D, the electrode holder 20 is preferably constructed from a single piece of molded medical grade EPDM rubber, such as compound L-5099. The electrode holder 20, provides a central hole portion 21, which allows access to the central well portion 22, and which passes down to the scalp surface. Electrolyte is injected through the central hole 21 to fill the central well portion 22 creating a bridge to conduct the electrical signal from the skin surface to the electrode (not shown), which rests on the ridge portion 23 located within the central well portion 22 of the electrode holder 20. On the side of the electrode holder 20, near the top, a hole 24 exists where a lead wire attachment portion of the electrode (not shown) extends from the electrode holder. On the outside portion of the electrode holder 20, an indentation 25 exists in which two O-rings 26 are used to capture the elastic fabric of the cap 10 from above and below when the electrode holder is pushed through the elastic cap fabric 10.

As shown in FIGS. 3A – 3C, the electrode 30 of the present invention has a flat disk portion 31 with a central hole 32. The electrode 30 also includes a lead wire attachment portion 33, which extends outward from the flat disk portion 31 and provides a pathway 34. Such a pathway may be created by drilling or by other mechanisms. The drilled pathway 34 provides an opening in which the lead wire 13 passes and is attached to the electrode 30 by crimping the attachment portion 33 onto the lead wire 13.

In a typical assembly sequence, an O ring is slipped over the lead wire 13. The electrode 30 is inserted into the central well portion 22 of the electrode holder 20 and rests on the ridge portion 23 to ensure correct placement. The electrode holder is inserted through a button hole or other opening in the elastic fabric cap and secured by positioning one or more O-rings over the fabric. The lead wire 13 is placed into the pathway 34 and the attachment portion 33 is crimped onto the lead wire.

An alternative embodiment of the preferred electrode of the present invention is shown in FIGS. 4A – 4F, where typical cup shaped electrodes 40 may be composed of metal (such as those manufactured by Specialized Laboratory Equipment, 232 Selsdon Rd. South Croydon Surrey, UK, PN: BO196/02) or conductive plastic 41 (such as those manufactured by Plastics One, 6591 Merriman Rd., S.W., Roanoke, VA, PN: 36562). In a typical metal electrode, a central hole 43 exists to allow injection of electrolyte down to the skin surface. In addition, a well portion 44 is provided to hold electrolyte in contact with the electrode surface. In a typical conductive plastic electrode 41, a central hole 45 exists to allow injection of electrolyte down to the skin surface. Again, a well portion 46 is provided to hold electrolyte in contact with the electrode surface. Both types of electrodes 40 and 41, may be readily carried within the electrode holder 20 of the present invention.

An alternative embodiment of the preferred electrode of the present invention is shown in FIGS. 5A – 5D, where conductive plastic electrodes 50 (such as those manufactured by Select Engineering Inc., 260 Lunenburg St., Fitchburg, MA, PN: SRT-3001/LP/0.06) and carbon electrodes 51 (such as those manufactured by Select Engineering Inc., 260 Lunenburg St., Fitchburg,

MA, PN: SRT-2001/CF/40) are shown. In both cases the non-metallic nature of the electrode material makes them less susceptible to induced currents present in the MRI environment, as well as to other physiological artifacts caused by movement of the body within the MRI device. On the conductive plastic electrode 50, a lead wire attachment means 52 exists, which provides a surface where conductive epoxy (such as EPO-TEK E2101) is used to attach the carbon lead wire 13 to the conductive plastic electrode 50. On the carbon electrode 51, a well portion 53 exists to hold electrolyte in contact with the electrode surface. The lead wire 13 is attached to the carbon electrode 51 by use of conductive epoxy at the electrode attachment point 54. Both the conductive plastic electrode 50 and carbon electrode 51 may be carried within electrode holder 20 of the present invention.

An alternative embodiment of the preferred electrode of the present invention is shown in FIG. 6, where an implantible depth electrode assembly 60 (such as those manufactured by AD-Tech Medical Instrument Corp., 1901 William St., Racine, WI, PN: SP-10P) is used. The depth electrode assembly 60 of the present embodiment positions 10 discreet electrodes 61a-j in which each acquires signals from a different region of the brain. The depth electrode assembly 60 can be placed into the cortex of a patient to collect electrical signals from multiple deep regions of the brain simultaneously. The depth electrode assembly 60 would not be carried in the electrode holder 13 of the present invention but rather the lead wire harness assembly 14 directly interfaces to the depth electrode assembly Connection System 62.

An alternative embodiment of the preferred electrode of the present invention is shown in FIG. 7, where a subdural cortical surface electrode assembly 70 (such as those manufactured by AD-Tech Medical Instrument Corp., 1901 William St., Racine, WI, PN: T-WS-20) is used. In the example given, the subdural cortical surface electrode assembly 70 of the present embodiment positions 20 discreet electrodes 71a-t in a grid pattern in which each acquires signals from a different region of the brain. However, other subdural cortical surface electrode assemblies exist that provide different numbers of electrodes. Grids with up to 128 discreet electrodes (not shown)

are readily available commercially, but other numbers of electrodes may be used. The subdural cortical surface electrode assembly 70 can be placed on the cortex of a patient to collect electrical signals from multiple regions of the brain underlying the grid pattern formed by the electrodes of the assembly. The subdural cortical surface electrode assembly 70 would not be carried in the electrode holder 13 of the present but rather the lead wire harness assembly 14 would be directly connected to the subdural cortical surface electrode assembly Connection System 72.

An alternative embodiment of the preferred electrode of the present invention is shown in FIG. 8, where a subdural cortical surface electrode assembly 80 (such as that manufactured by AD-Tech Medical Instrument Corp., 1901 William St., Racine, WI, PN: T-WS-8) is used. The subdural cortical surface electrode assembly 80 of the present embodiment positions 8 discreet electrodes 81a-h in a strip pattern in which each acquires signals from a different region of the brain. However, other subdural cortical surface electrode assemblies are readily available commercially that provide from 1 up to 128 discreet electrodes (not shown). The subdural cortical surface electrode assembly 80 can be placed on the cortex of a patient to collect electrical signals from multiple regions of the brain underlying the strip pattern formed by the electrodes of the assembly. The subdural cortical surface electrode assembly 80 would not be carried in the electrode holder 13 of the present invention but would be directly connected to the lead wire harness assembly 14 through the assembly Connection System 82.

In operation, the assembled Quik-Cap is placed on the patient's head and then, in appropriate embodiments, each electrode holder is filled with conductive electrolyte. Slight abrasion of the skin may be required during placement to reduce the impedance at the skin electrolyte interface to acceptable levels as determined by the input characteristics of the amplifier system to which the Quik-Cap assembly is attached.

In the manner described, the problems associated with collection of patient data in the environment of an MRI can be overcome.

What Is Claimed Is:

1. An electrode assembly, comprising one or more electrodes connected to electrode leads configured to carry electrical signals while operating inside a functional magnetic resonance imaging system during normal operation without interfering with the integrity of MRI data.

2. The electrode assembly of claim 1, in which the electrodes are manufactured from a material selected from a group comprising: Silver, Tin, Gold, Carbon, Platinum, Iridium, Tinsel, Stainless Steel, or an amalgam of Ag/AgCl or a combination of Conductive Plastic, Carbonized Plastic or Carbon Fibers.

3. The electrode assembly of claim 1, in which the electrodes are subdermal needles, subdural cortical surface electrodes, or subdural depth electrodes.

4. The electrode assembly of claim 1, in which the electrode leads are manufactured from a material selected from a group comprising Silver, Tin, Gold, Carbon, Platinum, Iridium, Tinsel, Stainless Steel, or an amalgam of Ag/AgCl or a combination of Conductive Plastic, Carbonized Plastic or Carbon Fibers.

5. The electrode assembly of claim 4, in which the electrode leads are manufactured from Carbon.

6. The electrode assembly of claim 4 in which at least two electrode leads are enclosed by a flexible material.

7. The electrode assembly of claim 6 in which the flexible material is configured to prevent coiling of said electrode leads.

8. The electrode assembly of claim 1, in which the electrode leads conduct signals over more than 10 feet distance without amplification.

9. The electrode assembly of claim 1, in which each of said one or more electrodes is positioned within an electrode holder.

10. The electrode assembly of claim 7, in which the electrode holder contains an opening through which electrolyte can be applied to a patient.

11. The electrode assembly of claim 7, in which the electrode holder is configured to accommodate one or more O-rings.

12. The electrode assembly of claim 7, in which the electrode holder is made of a flexible material.

13. The electrode assembly of claim 10, in which the electrode holder is made of rubber.

14. The electrode assembly of claim 1, in which a plurality of electrode holders is mounted to an elastic cap for placement on a patient's head.

15. An electrode assembly, comprising one or more electrodes connected to electrode leads configured to carry electrical signals while operating within an MEG imaging system during normal operation without interfering with integrity of data being captured.

16. An electrode assembly, comprising one or more electrodes connected to electrode leads configured to carry electrical signals while operating inside an environment in which at least one of an MEG imaging system and a functional magnetic resonance imaging system are operational without interfering with integrity of data being captured.

17. An transducer lead assembly, comprising one or more connection leads configured to carry electrical signals while operating inside a functional magnetic resonance imaging system during normal operation without interfering with integrity of MRI data.

18. The transducer lead assembly of claim 17 in which at least one connection lead is configured to carry signals from a source of signals comprising one of a group comprising: EOG signals, EMG signals, ECG signals, and signals to or from transducers for measuring impedance, skin conductance, acceleration, motion, or respiration.

19. An electrode assembly, comprising one or more electrodes connected to electrode leads configured to carry electrical signals while operating inside an environment in which at least one of an MEG imaging system and a functional magnetic resonance imaging system are operational without interfering with integrity of data being captured in which at least one of electrodes and electrode leads are held in place by flexible wrapping material.

20. A method of collecting electrical data during normal operation of a functional MRI without interfering with integrity of MRI data, comprising the step of using a non-ferromagnetic material for at least one of an electrode or a lead wire.

21. The method of claim 20 in which said non-ferromagnetic material is one of a group comprising: Silver, Tin, Gold, Carbon, Platinum, Iridium, Tinsel, Stainless Steel, or an amalgam of Ag/AgCl or a combination of Conductive Plastic, Carbonized Plastic or Carbon Fibers.

22. The method of claim 20, further comprising the step of mounting an electrode holder in a flexible cap.

23. The method of claim 22, further comprising the step of wrapping lead wires with a flexible material.

24. The method of claim 22, further comprising the step of securing said flexible cap to a head using a strap.

25. The method of claim 24, further comprising the step of adjusting the length of the strap using at least one a Velcro™ connection between the strap and the cap.

26. The method of claim 20 further comprising the step of mounting at least one of the electrodes and electrode wires to a patient using flexible wrapping.

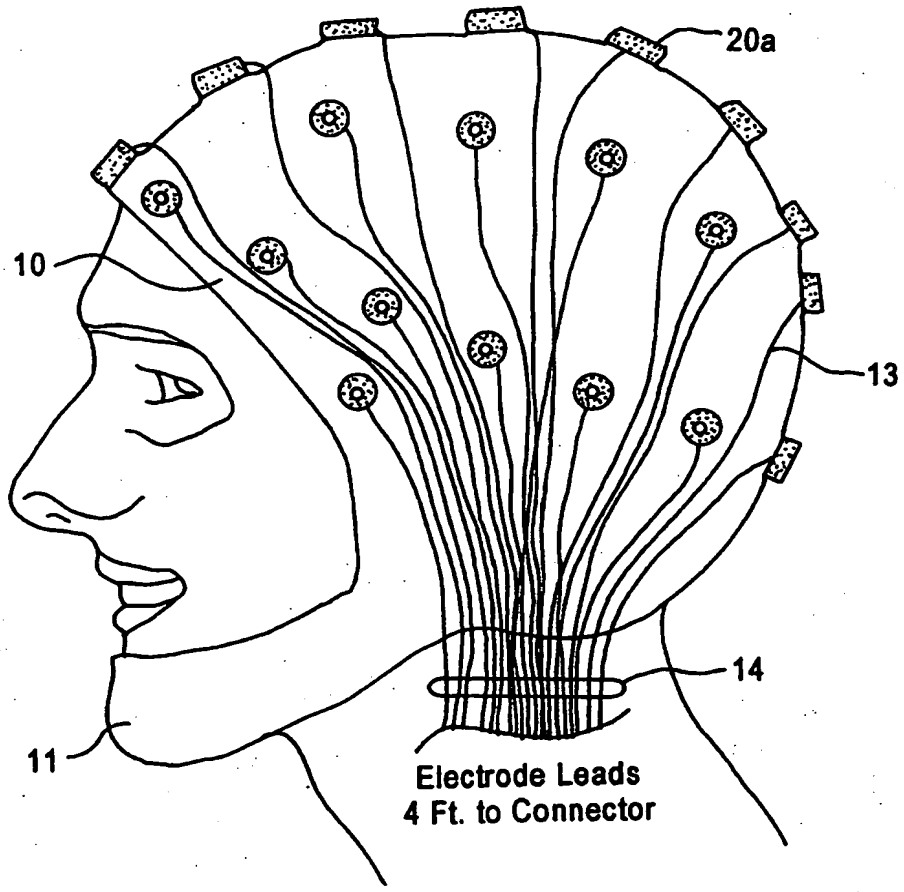


FIG. 1

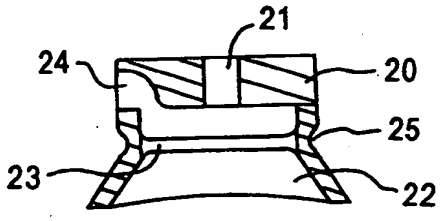


FIG. 2A

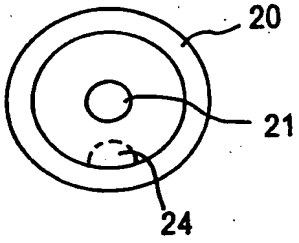


FIG. 2B

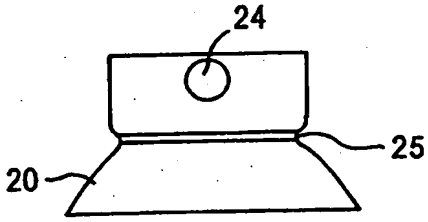


FIG. 2C

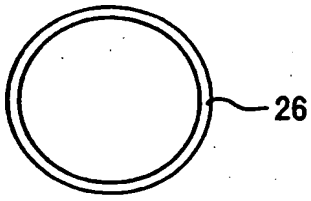


FIG. 2D

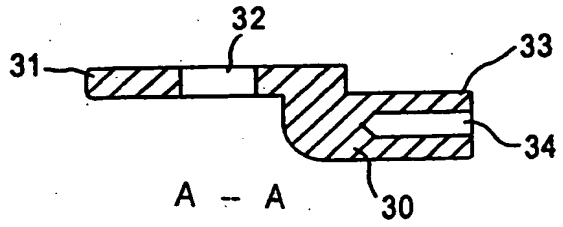


FIG. 3A

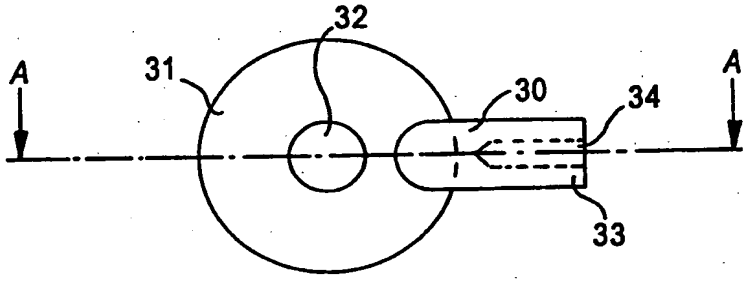


FIG. 3B

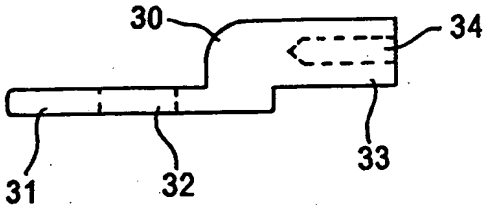
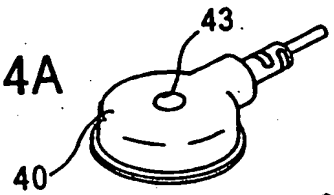


FIG. 3C

FIG. 4A



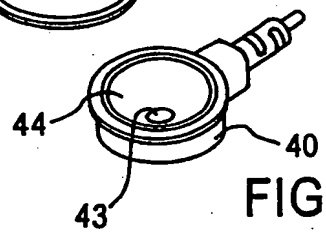


FIG. 4B

FIG. 4C

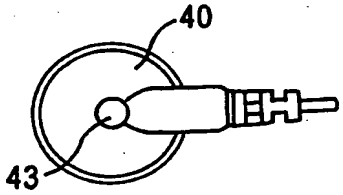


FIG. 4D

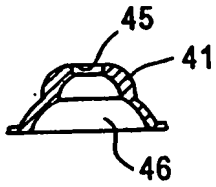
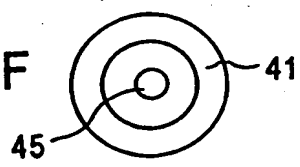


FIG. 4E

FIG. 4F



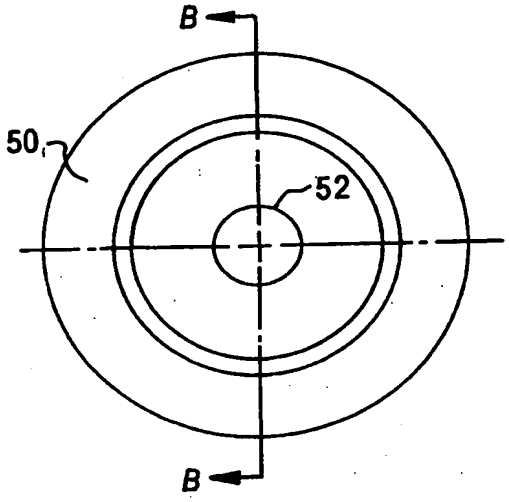


FIG. 5A

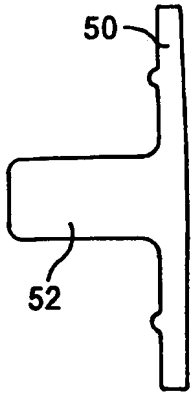


FIG. 5B

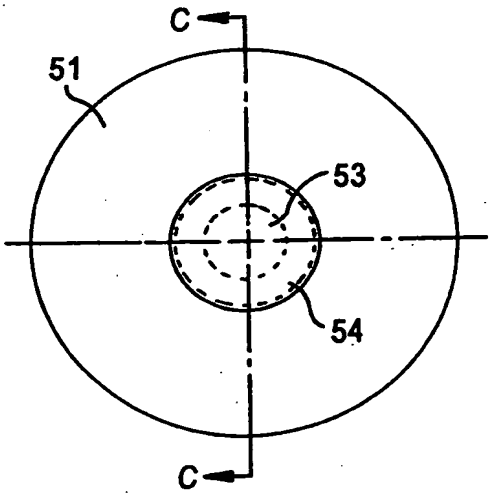


FIG. 5C

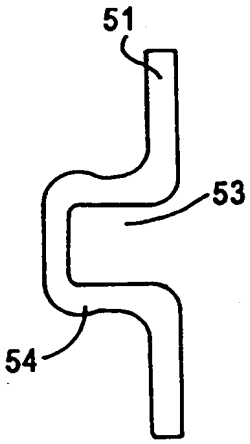


FIG. 5D

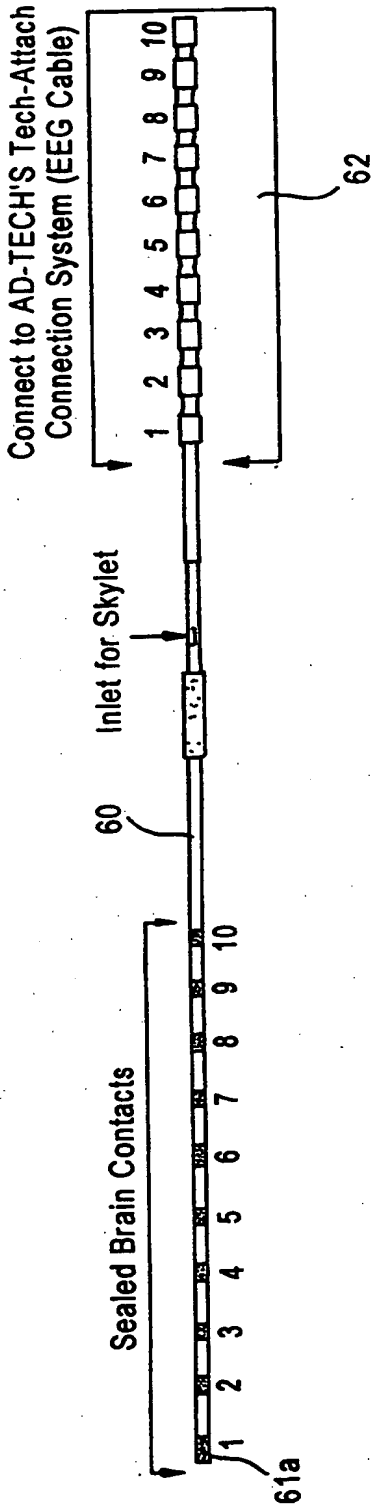

Connect to AD-TECH'S Tech-Attach Connection System (EEG Cable)
1 2 3 4 5 6 7 8 9 10
62
Inlet for Skylet
60
Sealed Brain Contacts
1 2 3 4 5 6 7 8 9 10
61a

FIG. 6

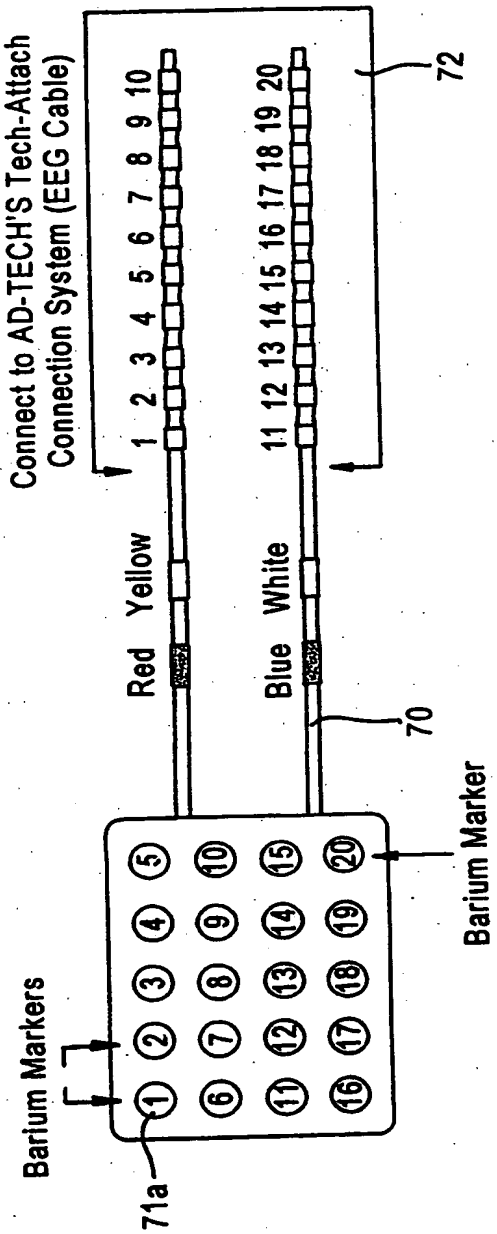

Connect to AD-TECH'S Tech-Attach
Connection System (EEG Cable)
1 2 3 4 5 6 7 8 9 10
11 12 13 14 15 16 17 18 19 20
72
Red Yellow
Blue White
70
Barium Marker
Barium Markers
71a

FIG. 7

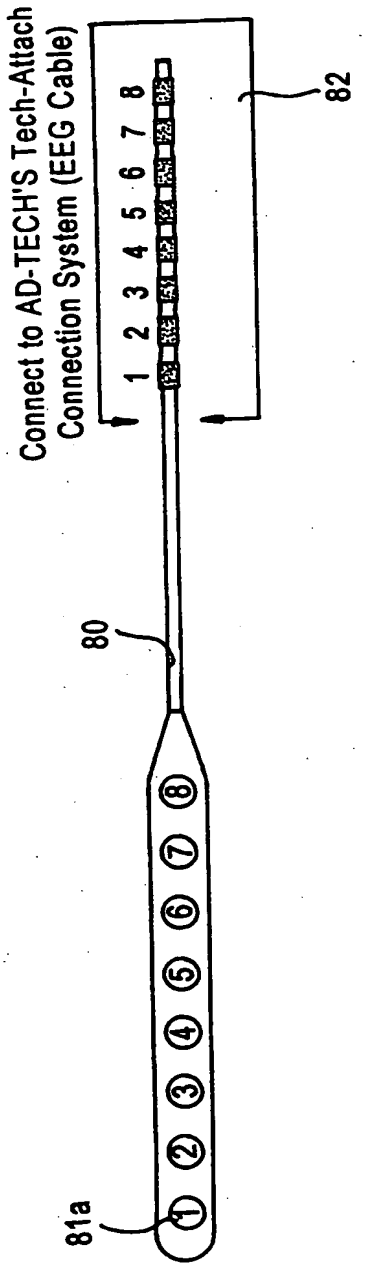

Connect to AD-TECH'S Tech-Attach
Connection System (EEG Cable)
1 2 3 4 5 6 7 8
82
80
81a
1 2 3 4 5 6 7 8

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/26459

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/04
US CL :600/372, 382, 383

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/372, 382, 383

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST 1.1a
Search Terms: MRI and electrode leads

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,217,010 A (TSITLIK et al.) 08 June 1993, Abstract, Figs.1-8b, and col.8 lines 30-32.	1, 3, 16-18 --- 2, 4, 6
X	US 5,044,368 A (PUTZ) 03 September 1991, Figs.1-3; col.5 lines 47, 48 and 57; and col.3 lines 58-61.	1-3, 16-21, 26
Y	US 5,411,545 A (BREYEN et al.) 02 May 1995, col. 2 lines 37-59; and col.3 lines 31-33.	2, 4, 6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 10 JANUARY 2000	Date of mailing of the international search report 04 FEB 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CARL H. LAYNO Telephone No. (703) 308-3694

Form PCT/ISA/210 (second sheet)(July 1992)*

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☑ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☑ FADED TEXT OR DRAWING
- ☑ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.